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Award Number:
W81XWH-10-1-0981

TITLE:
A Comparison of Robotic, Body Weight-Supported Locomotor Training and Aquatic Therapy in Chronic Motor Incomplete Spinal Cord Injury Subject

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REPORT DATE:
October 2013

TYPE OF REPORT:
Annual

PREPARED FOR:
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
October 2013	Annual	30September2012-29Septmber2013

4. TITLE AND SUBTITLE

A Comparison of Robotic, Body Weight-Supported Locomotor Training and Aquatic Therapy i n Chronic Motor Incomplete Spinal Cord Injury Subject

5a. CONTRACT NUMBER
W81XWH-10-1-0981

5b. GRANT NUMBER
W81XWH-10-1-0981

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Kernan Orthopaedics and Rehabilitation Hospital
2200 Kernan Drive
Baltimore, MD 21207

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, MD 212702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for public release, distribution unlimited.

13. SUPPLEMENTARY NOTES

14. ABSTRACT

At the end of study year 3 we completed all expected enrollment as per protocol. All necessary IRB approvals were obtained, and all regulatory documents submitted including the annual IRB continuing review, this approval will be available early November. All study personnel hold current certifications in order to participate in research. Multiple meetings occurred, both in person (at ASIA conference in Chicago, May 2013) and via monthly teleconferencing in order to coordinate activities between the Baltimore and the Atlanta sites. Thirty-six research participants initiated the study (with 5 drop outs) by the September 30, 2013 end of enrollment date. Currently 5 participants remain in an intervention arm in Baltimore (with 2 finishing the study by mid-October); and 3 individuals remain active at Shepherd. We are on target to complete all interventions by April 2014. Screening data entry and analysis is initiated and we are eager to begin outcome data assessment. One manuscript is published, one is in press, and 6 presentations (platform and poster) occurred from our study proposal and screening data analysis to date.

15. SUBJECT TERMS
Motor Incomplete Spinal Cord Injury, Lokomat, Aquatic Therapy, Functional and Physiological Outcomes

16. SECURITY CLASSIFICATION OF:U			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
					USAMRMC
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**	UU	33	**19b. TELEPHONE NUMBER** *(include area code)*
U	U	U			

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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INTRODUCTION

The goal of this research is to compare the effects of three months, three times a week aquatic therapy with similar intensity robotically assisted, body weight supported aerobic treadmill training upon functional ambulatory ability, cardiovascular fitness, and metabolic changes in individuals with chronic (greater than 12 months post injury) motor incomplete spinal cord injury (MISCI). It is anticipated that 36 individuals with chronic MISCI will enroll in this study. We hypothesize that aquatic therapy will be more effective than robotically assisted aerobic locomotor training in improving functional ability as measured by timed walks, a gait mat device and community step activity monitors. Furthermore, we also hypothesize that aquatic therapy will be more effective than robotic locomotor therapy in improving cardiovascular fitness as measured by open circuit spirometry during arm ergometry in these individuals. This work will provide preliminary evidence-based information as to the efficacy of aquatic therapy and robotically assisted, body weight supported aerobic treadmill training in chronic spinal cord injury motor system rehabilitation. A need for empirical data exists, as there is little objective data examining either of these two interventions after spinal cord injury.

BODY

Statement of Work (SOW) Tasks are listed below, and are followed (in blue and bold font) with description of the actual accomplishments during this annual study period.

Task 1: Implement plans, obtain IRB study approval and start up. (Month 1-6)

1a. Complete the formal study protocol, case report forms, data collection sheets, and informed consent documents. Ensure consistency in these documents across the two sites. (Month 1-2)

1b. Concurrently submit the protocol and regulatory documents to the University of Maryland at Baltimore and the Shepherd Center IRBs. (Month 2-6)

1c. Obtain research certification for all study personnel if not already obtained. Renew this certification annually or as required.

1d. Once IRB approval has been obtained, submit the protocol and regulatory documents to the respective VA Research Committees and the Medical Executive committee at Kernan Hospital. (Month 3-6)

1e. Develop an organizational meeting in Baltimore or Atlanta to allow for concurrent initiation and coordination of the research study (Month 5-6).

1a-e. As reported in prior quarterly reports, all of these tasks were completed in alignment with the SOW.

Task 2: Implement Randomized Clinical Trail (Months 7-42)

2a. Initiate screening of potential individuals for the research study (General medical and ASIA examination, blood tests, EKG, Standing frame challenge) (Months 7-9)

2b. Obtain baseline measurements (VO_2max, Timed walked tests, GAITRite, Step activity monitor studies) on individual study participants as they pass screening.

2c. Initiate the stratified randomization of subjects into the Lokomat versus aquatic therapy protocols with exercise occurring 3 times per week for 3 months. (Months 7 -9)
2d. Recruit twelve individuals across both sites during year one (approximately six per site approximately equally divided between tetraplegic and paraplegic individuals (Months 7-19).
2e Obtain 3 month outcome measurements after participants complete their first exercise intervention (Months 10-39).
2f. Cross over participants to the other exercise intervention after outcome measurements have been performed (Months 10-42).
2g. Obtain 6 month outcome measurements after participants complete their second exercise interventions (Months 12-42).

2a,b,d. 30 individuals were screened in Baltimore with 27 progressing to study participation. Three potential participants failed to meet screening criteria and one potential participant deferred secondary to an orthopedic. Fifteen individuals were screened in Atlanta at the Shepherd Center and fourteen progressed to study participation. Participation included obtaining baseline measurements per SOW 2b. The delay, especially in Atlanta, was secondary to the long review time of study documents (consent forms and other IRB material, etc). The DOD IRB permitted Kernan recruitment to begin in April 2011, and Shepherd recruitment to begin in July 2011.
2c. Kevin Chen, our consultant statistician, created a blocked randomization schedule and maintains this schedule separate from participant recruiters and PIs.
2g. At the end of this reporting year, 27 participants completed the final data collection.

Task 3. Implement Analysis of Data, Presentation and Publication (Months12-45).
3a. Provide annual reports to the Data Safety Monitoring Board at the Baltimore site (Months 12-36).
3b. Compete proposed statistical analysis of the study data and submit the results for scholarly presentation and publication. In addition provide outcome information in the form of a report to the granting agency. (Months 36-45).

3a. The sixth DSMB report will be submitted November 2013 and will include both Kernan and Shepherd data as appropriate. The first five DSMB reviews were positive. University of Maryland Baltimore and the Shepherd Center IRB renewals were obtained and provided to DOD in November 2012. The 2013 IRB Continuing Review for University of Maryland and the Shepherd Center are submitted and the written report will be available by mid-November.
3b. Data analysis is not yet possible; however, two publications and 9 study related presentations were completed to date.

Presentations:
Relationships among Physical Activity Scale for Individuals with Physical Disability (PASIPD), Body Mass Index (BMI), and Peak Oxygen Consumption (V02peak) in Persons with Motor Incomplete SCI. Presented at:

1) Both as Best Neurological Research Presentation and poster at American Academy of Physical Medicine and Rehabilitation, Washington DC, October 2013.

2) ASIA conference Chicago, IL, April 2013

3) Baltimore VA Research Day April 2013

4) Accepted for Combined Sections Meeting, American Physical Therapy Association, February 2014

Atypical Autonomic Dysreflexia during Robotically Assisted Body Weight Supported Treadmill Training in an Individual with Motor Incomplete Spinal Cord Injury. Presented at

1) ASIA conference Chicago, IL, April 2013

2) Baltimore VA Research Day April 2013

3) Accepted for Combined Sections Meeting, American Physical Therapy Association, February 2014

Motor Incomplete Spinal Cord Injury Randomized Trial Comparing Aquatic Therapy & Robotic-Assisted Body Weight Support Treadmill Training.

1) Platform presentation by Peter Gorman MD: American Spinal Cord Professionals Annual Conference, Las Vegas, NV, Sept 2012.

2) Invited Healthcare Presentation by Paula Richley Geigle PT PhD: Motor Incomplete Spinal Cord Injury Randomized Trial Comparing Aquatic Therapy & Robotic-Assisted Body Weight Support Treadmill Training. World Aquatic Health Conference: Norfolk, VA, October 2012.

Manuscripts

1) Geigle P, Frye S, Perreault J, Scott W, Gorman P. Atypical Autonomic Dysreflexia during Robotically Assisted Body Weight Supported Treadmill Training in an Individual with Motor Incomplete Spinal Cord Injury. *J Spinal Cord Medicine*. 36(2): 153-156 (2013).
2) Gorman PH, Geigle PT, York H, Scott W. Reliability and Relatedness of Peak VO2 Assessments during Body Weight Supported Treadmill Training and Arm Cycle Ergometry in Individuals with Chronic Motor Incomplete Spinal Cord Injury. In press, *Spinal Cord*.

Prose Summary Description of Recruitment Accomplishments:

The first Baltimore recruitment actually started in April 2011. Since then 31 individuals were screened with 27 progressing to study participation. Atlanta study recruitment began in July 2011 with 15 individuals screened and engaged in study participation. Recruitment at both sites began as soon as the Department of Defense (DOD) IRB review was complete. In Baltimore 17 participants and at Shepherd 11 participants completed the entire study. Currently 8 individuals (5 in Baltimore and 3 in Atlanta) are in active intervention. Demographic breakdown for all screened individuals includes the following:

Status key: I=first exercise arm, II=second exercise arm

Site key: 1=Baltimore, 2=Atlanta

gender	Race/ethni	veteran	Age	Level	status	site
M	AA	no	41	C7	withdrawn-II	1
M	Asian	no	20	C5	withdrawn--I	1
F	Caucasian	no	48	T9	completed	1
M	Caucasian	no	36	T6	Screen failure: Open skin lesions	1
F	AA	no	28	T12	Screen failure: ASIA B	1
M	Caucasian	no	60	C5-6	completed	1
M	Caucasian	no	61	C5-6	completed	1
M	AA	yes	61	C4	completed	1
M	Caucasian	no	41	T1	withdrawn--I	1
M	Caucasian	yes	35	C4	completed	1
M	AA	no	51	T1	deferred start	1

M	AA	yes	65	L2	screen failure	1
M	Caucasian	no	51	C4	completed	1
F	Caucasian	no	44	T10	completed	1
M	AA	no	27	T1	withdrawn-I	1
M	Am Indian	yes	49	C8	completed	1
M	Caucasian	no	46	C4	completed	1
M	Caucasian	no	55	T1	completed	1
F	Caucasian	no	30	C7	completed	1
F	AA	no	53	C3	completed	1
M	AA	yes	48	C8	completed	1
F	Islander	no	65	T1	enrolled-II	1
M	Hispanic	no	46	C4	enrolled-II	1
F	Caucasian	no	58	T1	enrolled-II	1
M	AA	no	57	T7	screen failure	1
M	AA	no	27	C6	enrolled-I	1
M	Caucasian	no	32	C8	enrolled-I	1
F	Caucasian	no	54	T3	completed	2
M	Caucasian	no	39	C5	completed	2
M	Caucasian	no	60	C4	completed	2
M	Caucasian	no	37	T8	completed	2
F	Caucasian	no	27	T1	completed	2
M	Caucasian	yes	65	C2	completed	2
M	AA	no	41	T6	completed	2

M	AA	no	50	C2	completed	2
F	Caucasian	no	25	C4	completed	2
M	Caucasian	no	31	C4	completed	2
M	Caucasian	no	40	T4	completed	2
M	AA	no	50	C2	enrolled-II	2
M	AA	no	39	C2	enrolled-II	2
M	Caucasian	no	51	C1	enrolled-I	2
F	AA	no	47	C4	failed screening: bowel program, HTN	2

Participants who were withdrawn:

Five individuals at the Baltimore site where withdrawn from study participation. One enrolled participant (at the Baltimore site) was withdrawn at his fourth training Lokomat exercise session secondary to his inability to tolerate Lokomat setup. Specifically, the fourth and final session was terminated during the warm-up period after the participant reported experiencing a "burning" sensation in the left foot. This participant reported similar symptoms during the two prior Lokomat training sessions but he did not report this symptom to the research team during the set-up and acclimation sessions. The reported paresthesia was not in a classical neuro-anatomic distribution. For two of the last four attempted training sessions the participant actually reported paresthesia before leaving the exercise mat and being suspended in the Lokomat harness. To diminish or prevent this problem, the research team attempted to re-position the Lokomat straps, but was unsuccessful in ameliorating the condition during Lokomat suspension. The PI ultimately terminated the subject's participation for safety reasons.

The second participant was withdrawn on his 11th Lokomat session (after he completed the entire Aquatic therapy arm of the study with no problems) when asymptomatic autonomic dysreflexia (AD) occurred. This was detected after the participant described a 'feeling of warmth' while exercising on the Lokomat. The blood pressure taken at the time was 210/100 mmHg. The subject was otherwise asymptomatic, i.e. there was no headache or diaphoresis. The blood pressure returned to normal after the subject was taken out of the Lokomat straps. Several attempts were made to modify the straps to see if this elevation in BP could be avoided. Unfortunately it could not.

Autonomic dysreflexia is a known complication of persons with spinal cord injury at or above the T6 level, usually caused by some sensory irritation below the level of injury. We discussed this incident with the IRB at the time it occurred. Since AD is a known complication, no reportable new information (RNI) report was required. Because of the persistent elevation in BP during the Lokomat component of the protocol (i.e. silent AD), this individual was withdrawn from the study.

An unfortunate non-study activity related, lower leg fracture necessitated withdrawal of the third participant. He was casted for 6 weeks sp fracture.

An unreported skin irritation on the plantar surface of his foot facilitated the removal of the fourth research participant. This individual does not routinely examine his skin integrity, or follow up with recommended and scheduled clinical care. Once the irritation was researcher identified, the area was examined and treated until the participant no longer returned to our facility. Attempts were made to contact him via phone and mail with no success.

The fifth participant successfully completed the aquatic intervention and 30 sessions of Lokomat and was hospitalized for a non-study condition.

All of these withdrawn individuals but the fifth who was directly admitted to the hospital from home, were medically evaluated by the PI (PHG) who determined that no further intervention was necessary other than withdrawal from participation. Two withdrawn individuals are currently engaged in our wellness aquatic programs as a secondary outcome of study participation. We will continue to diligently monitor all study participants to insure safe participation in this DOD protocol. Additionally, study withdraws were reported through our established DSMB.

KEY RESEARCH ACCOMPLISHMENTS

- Completed the formal study protocol, case report forms, data collection sheets, and informed consent documents
- Ensured consistency in these documents across the two study sites
- Obtained necessary IRB (University of Maryland Baltimore, Shepherd, and DOD) study approval
- Filed required regulatory documents
- Obtained research certification for all study personnel if not already current
- Orchestrated organizational face to face meetings in Baltimore, Atlanta, and at national professional meetings to allow for concurrent initiation and coordination of the research study

- Held weekly DOD research study meetings (in Baltimore) including all local team members
- Planned and executed monthly phone conferencing between both study sites
- Scheduled weekly site meetings to discuss all aspects of this DOD study and review study protocol and procedures
- Submitted local IRB modification to clarify exclusion criteria so that they better align with the current clinical definition of diabetes; and to offer optional participation in MRI screening at pre, mid, and post data assessment for abdominal adiposity.
- Two manuscripts from screening data and study execution only
- Nine presentations from proposal, screening data, and study execution only:

Our plan for year four of the DOD study includes:

- Obtain 6 month outcome measurements after final eight participants complete their second exercise interventions
- Continue to provide quarterly and annual reports to the DOD and appropriate documentation to UMB IRB.
- Submit our sixth DSMB report in November 2013
- Continue to enter demographic and outcome data into our study database using the established common data base SCI template
- Analyze both screening and outcome data
- Draft publication(s) discussing: clinical concepts; cardiovascular; functional; and metabolic information learned from this DOD funded study
- Draft a final report for DOD

REPORTABLE OUTCOMES: No reportable outcomes available to date.

CONCLUSION: At the conclusion of year 3 of the DOD study we met all planned proposal activities: regulatory compliance, recruitment, data collection, and fiscal responsibility; and are well positioned to complete data entry and analysis as well as craft publications to disseminate these findings.

REFERENCES: NA

APPENDICES:

1) **Autonomic Dysreflexia published paper**
2) **Arm Ergometer and Lokomat Reliability manuscript (in press)**

Case report

Atypical autonomic dysreflexia during robotic-assisted body weight supported treadmill training in an individual with motor incomplete spinal cord injury

Paula R. Geigle[1], Sara Kate Frye[1], John Perreault[2], William H. Scott[2], Peter H. Gorman[2]

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Context/objective: A 41-year-old man with a history of C6 American Spinal Injury Association (ASIA) Impairment Scale (AIS) C spinal cord injury (SCI), enrolled in an Institutional Review Board (IRB)-approved, robotic-assisted body weight-supported treadmill training (BWSTT), and aquatic exercise research protocol developed asymptomatic autonomic dysreflexia (AD) during training. Little information is available regarding the relationship of robotic-assisted BWSTT and AD.

Findings: After successfully completing 36 sessions of aquatic exercise, he reported exertional fatigue during his 10th Lokomat intervention and exhibited asymptomatic or silent AD during this and the three subsequent BWSTT sessions. Standard facilitators of AD were assessed and no obvious irritant identified other than the actual physical exertion and positioning required during robotic-assisted BWSTT.

Conclusions/clinical relevance: Increased awareness of potential silent AD presenting during robotic assisted BWSTT training for individuals with motor incomplete SCI is required as in this case AD clinical signs were not concurrent with occurrence. Frequent vital sign assessment before, during, and at conclusion of each BWSTT session is strongly recommended.

Keywords: Autonomic dysreflexia, Body weight support treadmill training, Motor incomplete spinal cord injuries, Robotic-assisted exercise, Lokomat, Tetraplegia

Introduction

Autonomic dysreflexia (AD) occurs frequently in individuals with spinal cord injury (SCI) at level T6 or above, including both greater than 20–30 mmHg blood pressure (BP) change, and relative bradycardia (slow heart rate).[1,2] AD with elevated BP is a known risk factor for intracerebral hemorrhage, and therefore, is treated as a medical emergency.[3–5] AD can be precipitated by various afferent irritants from below the level of the injury particularly novel stimuli such as electrical stimulation and body weight supported exercise.[6] Alan *et al.*[6] reported that injury-induced vasculature changes may contribute to AD occurrence via circulatory changes and the altered ability to tolerate novel sensory input.

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The syndrome is commonly associated with headache and diaphoresis, but sometimes can be asymptomatic. There are reports of silent AD during voiding,[7] bowel programs,[8] sperm retrieval,[9] and possibly accupuncture.[10] It is unclear what long-term impact these large systolic blood pressure (SBP) changes cause, or what mechanism(s) stimulate these SBP fluctuations.[11] Upright walking-like exercise is also reported to increase BP via exaggerated spinal reflexes in individuals with SCI at T6 or above.[12]

The Consortium for Spinal Cord Medicine Clinical Practice Guidelines for the acute management of AD emphasize the need to be aware of AD symptoms, while noting that AD clinical signs are not always present.[4] Currently, it is unclear exactly how robotic-assisted BWSTT impacts potential AD. During BWSTT, autonomic regulation of BP is reported to

DOI 10.1179/2045772312Y.0000000033

improve, with a positive impact upon blood flow in the femoral and carotid arteries is reported.[13] Krassioukov and Harkema[14] reported the need to carefully assess cardiovascular responses in individuals with upper thoracic and cervical SCI while in the BWSTT harness system, finding significant increase in arterial pressure while sitting in the harness. This pressure abrogated, however, when standing without gait training. This case report details the potential relationship between robotic-assisted BWSTT and AD in an individual with C6 AIS C chronic SCI.

Case report

A 41-year-old African–American man with C6 ASIA Impairment Scale (AIS) C Impairment Scale tetraplegia secondary to a sports injury 23 years ago participated in a body weight-supported robotic treadmill training (BWSTT) and aquatic exercise research protocol. The participant enrolled in an ongoing randomized clinical trial, approved by the University of Maryland Baltimore and Department of Defense Institutional Review Boards, to evaluate the cardiovascular and mobility effects of 3 months of robotic-assisted BWSTT exercise versus 3 months of aquatic-based exercise in people with chronic (>1 year) cervical and thoracic motor incomplete SCI. Therapist-directed exercise interventions under each arm of the protocol occurred three times per week, every other day, for 40 minutes in an outpatient rehabilitation setting.

This patient uses a power wheelchair for mobility and is actively employed as a computer programmer specialist. His spasticity, primarily of the lower extremities, is well managed with oral baclofen at 10 mg three times per day. He manages his bladder with external condom catheter drainage and his bowel routine includes every other day bisacodyl suppositories. His remote history includes renal stones and headache in the context of bladder distension and the passage of renal calculi. Serial imaging studies of his collecting system during the last few years, however, demonstrated no hydronephrosis or renal stones, and serial blood tests document normal renal function.

Randomized to start in the aquatic therapy intervention, J.W. completed 36 aquatic therapy sessions over 12 weeks with no known AD occurrence. Vital signs were assessed at the beginning and end of each aquatic therapy session with no significant changes noted. BP readings were also unchanged during peak VO_2 arm ergometry testing, a study outcome measure, and during his pre-study standing frame assessment.

The robotic-assisted BWSTT (Lokomat®) intervention consisted of the standard partial weight support using the appropriate straps, harness system, and limb lengths based on prior measurements. Weight support was initiated at 80–100% with treadmill speed initiated at 1.5 mph (0.42 m/second) to 1.8 mph (0.5 m/second) km/hour and adjusted to the predetermined optimal treadmill speed (3.2 mph as a target) measured during the acclimation training session. Treadmill speed was modified, as tolerated, to provide an additional aerobic challenge during the peak assessment. J.W. viewed his effort via the real-time visual feedback of lower extremity force on a screen display. A Polar® monitor recorded continuous heart rate.

J.W.'s initial nine Lokomat sessions were significant only for some minor knee pain, which resolved spontaneously, and discomfort from the harness, which was resolved with repositioning. On the 10th session, pre-exercise BP was 104/52. Twenty minutes into the session, JW complained of exertional fatigue. The Lokomat was stopped. BP at that time was 220/80 mmHg and rose to 260/110 mm/Hg on a repeat measure with no symptoms other than exertional fatigue. Upon removal from the BWSTT device, his BP quickly fell to 98/50 mmHg. No skin changes were noted as possible friction points. The Lokomat straps were not obstructing urine flow from his external collecting system. No other alternate cause for the BP change could be found. The subsequent three sessions followed a similar course with regard to BP and the lack of any AD clinical symptoms; exertional fatigue only occurred during 10th session (Table 1). A pre-exercise post-void residual obtained before the 12th session was unremarkable. Seated BPs in the harness before and after suspension were normal prior to robotic activation and without volitional movement. BP rose sharply only after commencing the 10th robotic-assisted BWSTT exercise session. The participant's BP returned to normal immediately following the termination of each session. J.W.'s participation in the research study was terminated due to concern about these repeated episodes of symptomatic elevation in BP during robotic-assisted BWSTT.

Discussion

This individual with long-standing motor incomplete tetraplegia experienced atypical AD during the active component of robotic-assisted BWSTT training using the Lokomat device. This finding was replicated across four different sessions on four different days. He experienced no recent similar episodes but has a past history of AD-associated headache during voiding. This was associated with renal stone disease with 1–2 episodes of symptomatic dysreflexia in 23 years, and none in the past 10

Table 1 BWSTT BP and heart rate response data

	Pre-exercise		Average exercise BP (two readings)		Post-exercise	
Session	Seated BP	Seated HR	Standing supported BP	Standing supported HR	Seated BP	Seated HR
10	104/52	67	240/95	84	98/50	NA
11	102/62	69	184/97	77	77/53	101
12	108/50	77	175/90	82	80/58	NA
13	94/60	NA	210/98	NA	90/60	NA

BP, blood pressure (mmHg); HR, heart rate (bpm); Session refers to BWSTT training sessions within the protocol.

years. He described headache and flushing as symptoms of his prior symptomatic dysreflexia. Being strapped into the BWSTT harness with body weight unloaded did not appear to be directly causal to the elevation of BP, because it was only during the aerobic exercise facilitated by the robot exoskeleton that the BP sharply increased. In addition, J.W.'s vital signs taken during screening in the standing frame did not display signs of dysreflexia during the 30-minute time span (Table 2). The clinical decision was made to stop further robotic-assisted BWSTT because of this asymptomatic AD and the concern that this activity might be harmful.

Prior to BWSTT, this individual tolerated rather strenuous aerobic exercise in an upright position in an aquatic environment without observed adverse BP changes. However, midpoint BP readings were only completed through the first eight aquatic sessions with no abnormal BPs obtained. Additionally, during aggressive arm cycle ergometry BP was assessed at several midpoints with no abnormal elevation. The combination of the harness system and the aerobic stimulus (rate perceived exertion 10/10) in this individual seemed to be a crucial AD precipitating factor. With harness suspension and aerobic exercise, the modulation of vascular and sensory feedback may be diminished secondary to the SCI.[12,14] A larger clinical matter, is the health cost-benefit analysis of exercise on cardiovascular health and the potential AD which may occur during robotic-assisted BWSTT for individuals with level of SCI at or above T6.[11,13,14–16]

The presence of atypical AD in this case report provides evidence that one individual with incomplete SCI experienced sharply increased BP during robotic-assisted BWSTT activities with exertional fatigue reported in only the 10th session manifesting as the only AD clinical symptom. Identification of AD may be confounded as symptoms such as perspiration and flushing occur with aerobic exercise. Both aerobic exercise exertion and AD may be new occurrences; therefore, it may be difficult for the individual with SCI as well as the practitioner to identify the precise cause. More research is indicated to investigate how SCI affects cardiovascular function across the lifespan. The stimuli of these BP fluctuations are unknown, but silent AD may have serious, even fatal consequences, and should thereby be monitored and avoided as part of best practice.[16]

Table 2 Screening standing frame heart rate and BP data

Time (minutes)	Blood pressure (mmHg)	Heart rate (bpm)
0	106/66	75
5	102/60	82
10	84/60	80
15	98/58	80
20	102/65	94
25	104/62	79
30	92/60	88

Conclusion/clinical relevance

This experience with robotic-assisted BWSTT provides data indicating the development of AD during Lokomat training for one individual with motor incomplete tetraplegia or paraplegia above the T6 level. Increased awareness of AD occurring during BWSTT for individuals with motor incomplete SCI is recommended for all clinicians conducting robotic-assisted BWSTT interventions. Frequent vital sign assessment before, during, and at the conclusion of each BWSTT training session is recommended to prevent possible complications from silent AD.

With the advent of increased access to aquatic exercise and BWSTT, it is equally important to assess midpoint BP on all individuals with SCI exercising at moderate to high intensity. Currently, we use a wrist cuff to provide easier midpoint BP and heart rate data during both aquatic and Lokomat sessions. These devices require a short interruption of exercise for 30 seconds. Investigation is ongoing of a system capable of providing BP data during Lokomat sessions.

Acknowledgements

This work was supported by the US DOD Clinical Trial Award SC090147. We thank JW for participating in this randomized clinical trial, and for agreeing to report his case. Thanks to Jean McQuaid PT and Naomi Miller

Price PT for providing the therapist direction during robotic-assisted BWSTT; Rosalyn Lobo PT, Neshelle Bragg PT, Michelle J. Daniels, PT, DScPT, who provided aquatic intervention; Gertrude Morrison Research RN for recruitment/screening assistance, and to Leigh Casey for manuscript preparation assistance.

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Reliability and Relatedness of Peak VO_2 Assessments during Body Weight Supported Treadmill Training and Arm Cycle Ergometry in Individuals with Chronic Motor Incomplete Spinal Cord Injury

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Abstract

Study Design: Prospective assessment as part of initial evaluations for randomized controlled trial (RCT) participation.

Objectives: To assess the test-retest reliability of peak VO_2 testing during both robotically assisted body weight supported treadmill training (RABWSTT) and arm cycle ergometry, and to determine the relationship between the two measurements in individuals with chronic motor incomplete spinal cord injury (CMISCI).

Methods: Twenty-one participants with American Spinal Injury Association Impairment Scale (AIS) C and D spinal cord injury enrolled in a three month, RABWSTT randomized controlled trial. As part of their baseline assessments, these individuals underwent VO_2 peak assessments twice on separate days during both RABWSTT and arm cycle ergometry using a metabolic cart.

Results: Peak oxygen consumption measured at baseline correlated significantly between repeated tests in the RABWSTT ($r = .96$, $p < 0.01$) and the arm ergometer ($r = 0.95$, $p < 0.01$). A significant positive correlation ($r = 0.87$, $p < 0.01$) existed between the peak $V0_2$ measurements obtained using RABWSTT and arm cycle ergometry.

Conclusions/Clinical Relevance: Determination of VO_2 peak during both RABWSTT and arm ergometry in individuals with CMISCI is highly reproducible. Furthermore, a strong correlation exists between peak VO_2 measured during RABWSTT and arm cycle ergometry in this population. This correlation offers implications for future cardiovascular testing of individuals with CMISCI as two reproducible peak $V0_2$ measurement techniques are possible.

Sponsorship: Department of Veterans Affairs Rehabilitation R&D Service Merit Review Award B40271.

Key words: robotically assisted body weight supported treadmill training, chronic motor incomplete spinal cord injury, Peak VO_2, reproducibility, validity

Introduction

Individuals with spinal cord injury (SCI) experience decreased lean muscle mass and increased total body and abdominal fat, predisposing them to a higher incidence of diabetes, hypertension, and dyslipidemia than able-bodied people [1-4]. These problems, in part, are caused by neuromuscular limitations following injury and the subsequent associated sedentary lifestyle. Physical activity is recommended to combat these health related problems. Unfortunately, the person with SCI holds limited activity options. Several evidence-based guidelines exist for the able-bodied population, including the Adult Treatment Panel III, which recommends aerobic exercise to achieve cholesterol modification and weight reduction [5, 6]. However, specific available exercise guidelines are limited for individuals with SCI; and the associated restricted muscle activation, secondary metabolic derangements, and barriers to accessing exercise opportunities may limit activity engagement [7-9]. This lack of optimal aerobic exercise recommendation for individuals with SCI partially stems from limited information about exercise peak VO_2 responses, a primary dependent variable for determining adequate aerobic training. These cardiovascular measures are difficult to reliably assess on the 'gold-standard' treadmill because muscle weakness, gait disturbances and/or use of assistive devices all may interfere with peak $V0_2$ assessment. Measurement of peak VO_2 assessed via arm cycle ergometry for individuals with CMISCI is currently utilized [10-12], but the relationship between upper and lower extremity exercise is not previously reported.

Various robotic treadmill training devices provided lower extremity movement assistance for individuals with gait deficits. One device, the Lokomat®, an exoskeletal robotically assisted, body weight supported treadmill training (RABWSTT) device (Hocoma AG, Zurich, Switzerland), is included in treatment and exercise programs for individuals with MISCI.[13] The impact of Lokomat training upon the cardiovascular system of individuals with MISCI is limited[14] with little information available addressing if peak VO_2 response can be effectively and reliably obtained during robotic assisted exercise. The relationship between peak VO2 measurements during robotic treadmill

training and arm cycle ergometry is unknown. This information would be useful to better understand the impact of exercise interventions upon the cardiovascular fitness of individuals with MISCI.

This paper reports the test-retest reliability of both RABWSTT and arm cycle ergometer devices while eliciting peak VO_2 response in individuals with chronic motor incomplete spinal cord injury (CMISCI). Additionally, for the same population, we assess the relationship between arm cycle ergometry as the accepted tool and RABWSTT to facilitate peak VO_2.

Materials and Methods

Participants

Twenty-one individuals with chronic (> one year post injury) motor incomplete spinal cord injury (19 males and 2 females) with ASIA Impairment Scale (AIS) C (2) or D (19) between the ages of 25-72 (average = 51.1 ± 13.7 years) agreed to participate in a three month training, randomized controlled trial to determine the RABWSTT effectiveness on gait function and aerobic capacity (Table 1). Participants were a convenience sample recruited from the outpatient SCI clinics at an academically affiliated 132 bed rehabilitation hospital center and an academically affiliated outpatient Department of Veterans Affairs SCI support team clinic within the same city. Eligible participants sustained a spinal cord injury at least 12 months prior to enrollment, were between 18 and 80 years old, with a confirmed level of injury between C4 and L2, and AIS of either C or D. Study participants were required to tolerate 30 vertical minutes in a standing frame, but community ambulation was not a requirement. Individuals were excluded with a history of uncontrolled hypertension, unstable angina, congestive heart failure, chronic obstructive pulmonary disease, symptomatic peripheral arterial occlusive disease or recent (within the last 3 months) hospitalization for any medical problem. Individuals with severe contractures or frequent uncontrolled bouts of autonomic dysreflexia were also ineligible.

Methods

Baseline evaluations included a full history and physical examination, electrocardiogram, and serum laboratory tests to screen for renal disease, liver disease and uncontrolled diabetes. Neurologic assessments were completed using the International Standards for Neurological Classification of Spinal Cord Injury. As part of the baseline testing for randomized trial, all participants also underwent Dual Energy X-ray Absorptiometry testing as well.

Lokomat Testing

All participants completed two to three 20 minute acclimation training sessions in the Lokomat prior to the measurement of peak aerobic capacity in the device with sessions designed to expose participants to the body weight support (BWS) system (0-100%) and treadmill speed (1.6-3.2 kph). Participants performed a three minute warm-up phase in the Lokomat at the start of the peak VO_2 test with the initial work rate settings at 1.5 to 1.8 kilometers per hour (kph) for treadmill speed with robotic BWS maintained at 100%. Next, the exercise phase was initiated to induce a peak VO_2 response by periodically modifying work rates (speed and BWS) every 2-3 minutes, and treadmill speed was increased by 0.2 to 0.3 kph during these adjustment intervals. Using visual gait assessment the physical therapist reduced BWS during these adjustment intervals ideally minimizing BWS while maintaining the desired gait pattern. Participants were instructed to actively assist the robot through the gait-cycle to generate a cardiac "workout", and the RABWSTT LCD screen provided visual feedback of participant effort. Termination of each test (9-15 minutes) occurred with volitional fatigue or if the participant was unable to perform the required work rate with an appropriately aligned gait pattern.

Arm Cycle Ergometry Testing

An exercise physiologist administered all arm cycle and RABWSTT protocols including a graded exercise paradigm with periodic work rate increases until volitional fatigue occurs.

Participants performed two peak VO_2 arm cycle ergometer tests using a standard desktop mounted device (Figure 1b) with a 3-5 minute warm-up at zero resistance using a self-selected pedal cadence. The exercise phase followed this warm-up period with the work rate adjusted every minute by increasing the resistance to the flywheel, and instruction given to maintain a self-selected rotational cadence at each new work rate. Termination of each peak test occurred at volitional fatigue or if participants could not maintain the self-selected pedal cadence. If needed, hand stability positioning straps were utilized during arm cycle ergometry.

Determination of Peak VO2 values

For both the Lokomat and arm cycle ergometer tests, air flow and gas exchange data was continuously monitored with the VMAX Encore Metabolic Cart (Sensormedics a subsidiary of VIASYS Healthcare, Inc, Yorba Linda, California), an open circuit spirometry device used to determine oxygen consumption (VO_2) and carbon dioxide production (VCO_2). To collect the gases, participants donned a Hans Rudolph mask which interfaced to the metabolic cart through a flow meter and sample lines. Figures 1a and 1b illustrate this set-up procedure in both test modalities (RABWSTT and arm cycle ergometry). A computer software program integrated the data to provide VO_2, VCO_2 , pulmonary ventilation (VE) and respiratory exchange ratio (RER) (expired VCO_2/VO_2 consumed) every 20 seconds. Our final VO_2 peak value averaged the two highest consecutive 20-sec sampling points.

Statistical Analyses

Determination of the test-retest reliability of both the arm cycle ergometer and RABWSTT to induce peak $V0_2$; and the RABWSTT $V0_2$ and arm cycle ergometer $V0_2$ relationship occurred. Individual person data was normalized to body weight in kilograms for each subject. A correlation coefficient indicated the reliability of the repeated measures for the VO2 measurements on each device separately. High reliability was defined as an r value greater than 0.85[15]. We also assessed the two VO2 peak data from the two devices (Lokomat and arm ergometer) to examine any existing relationship.

Statement of Ethics

The University of Maryland Baltimore Institutional Review Board, the Baltimore VA Medical Center (VAMC) Research Committee, and the Kernan Hospital Medical Executive Committee approved this protocol. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

Results

Twenty one participants tolerated two sessions each of RABWSTT and arm cycle ergometry testing. There were 15 individuals with tetraplegia based on total ISNCSCI assessment with nine of them at C4 or above and six at C5 to C8. Six individuals displayed paraplegia, five from T1 to T12 and one at L2. The participants displayed an average body mass of 83.3 kg (± 19.8 SD, range 45.8-129.8) and average body fat of 33.7 percent (± 7.6 S.D, range 22.2-44.6). Individuals varied widely in their peak VO_2 measurements. For the RABWSTT paradigm, peak VO_2 measurement ranged from 6.1 to 37.6 ml/kg/min with an average of value 15.1 ± 5.5 for test 1 and 15.8 ± 6.8 for test 2. The results for the arm cycle ergometry paradigm ranged from 9.3 to 36.5 ml/kg/min with an average of 16.3 ± 6.4 for test 1 and 16.7 ± 4.9 for test 2. Peak oxygen consumption measured at baseline correlated significantly between repeated tests in the RABWSTT ($r = 0.96$, $p < 0.01$) (Figure 2) and the arm cycle ergometer ($r = 0.95$, $p < 0.01$) (Figure 3). Significant positive correlation ($r = 0.87$, $p < 0.01$) also occurred for the comparison of average (test 1 and test 2) Peak $V0_2$ measurements obtained using RABWSTT and arm cycle ergometry. (Figure 4)

Discussion

We are among the first research groups to investigate the test-retest reliability of peak oxygen consumption measurement using the RABWSTT and arm cycle ergometry, and evaluate the relationship between RABWSTT and arm cycle ergometry peak VO_2 measurements for individuals with CMISCI. Investigation into test-retest reliability of arm cycle ergometry peak $V0_2$ is important to understand as currently it is not yet a fully standardized cardiovascular assessment tool for

individuals with CMISCI. It is however used clinically in cardiac stress testing protocols for people with lower extremity paralysis in situations where pharmacologic (thallium) stress testing is not desirable. Those with incomplete paralysis, who are unable to undergo standard treadmill exercise testing, are able to train and test their cardiovascular system with RABWSTT. As RABWSTT conditions are increasingly used for cardiovascular (CV) testing and fitness training in individuals with CMISCI, it is important to understand the reproducibility and relatedness of this technique to the arm cycle ergometry standard. In this population, the neurologic impairment often includes autonomic impairment, offering altered heart rate and blood flow responses that could potentially dissociate the CV effects of upper body exercise from those of lower body exercise. It is important to establish this relationship between arm cycle ergometry and RABWSTT as we employ increased interventions to improve CV fitness for individuals with CMISCI.

Arm cycle ergometry testing

Bulthuis et al reported the arm crank is a reliable tool to measure VO_2 peak during exercise as well as sub-maximal VO_2 in able-bodied subjects.[16] Using a six-minute arm cycle testing paradigm, Hol et al stated a similar result for a cohort of individuals with SCI [12] with mean VO_2 peak 18.6 ± 8.4 mL/kg/min, similar to our results. Hol et al concentrated on a measure of VO_2 at sub-maximal effort based on a desire to maintain constant power output during the six minutes. This was not our emphasis however, we aimed to correlate the peak measurement, which is considered the criterion standard of cardiovascular fitness during treadmill exercise testing. Sub-maximal steady state exercise would be difficult to standardize using RABWSTT given the anticipated injury variability encountered in this population.

Upright RABWSTT testing

Researchers examining the cardiovascular (CV) fitness parameters including VO_2 peak of individuals post stroke report strong test-retest reliability utilizing treadmill exercise assessments.[17, 18] However,

an important difference exists between individuals post stroke and post CMISCI related to CV fitness testing with the standard treadmill testing protocol. For people with CMISCI especially those who are non-ambulatory in the community, CV fitness assessment on a treadmill may not be possible without robotic assistance. Additionally, altered autonomic responses to upright exercise might hamper results, although in this cohort, there were no major autonomic problems (either with hypotension or dysreflexia) during exercise. Passive robotic gait training without some voluntary effort would be insufficient to increase cardiopulmonary fitness in people with SCI. In a case report, researchers demonstrated that body weight supported treadmill training needed active exercise engagement to achieve the desired training intensity as monitored by VO_2.[14] Jack et al investigated the impact of body weight supported treadmill exercise upon the cardiopulmonary fitness of two men with CMISCI indicating an improvement in V02 peak.[19] Consistent with our test-retest findings, this research group also reported a high reliability (r=0.95), for peak $V0_2$ measured during RABWSTT in a study consisting of nine men with CMISCI. [20] They concluded that robotically assisted training could be an adequate stressor of the cardiovascular system when compared in a similar way to arm crank ergometry.

Our work supports the Lokomat, a RABWSTT robotic device, besides being an exercise training choice, can be employed as a reliable and valid tool to facilitate an appropriate aerobic work challenge when assessing peak oxygen consumption for individuals with CMISCI. Our work provides further evidence of an existing relationship between VO_2 peak with upper extremity exercise and using robotically assisted leg exercise in persons with CMISCI. As we focus upon improving cardiovascular health for individuals with MISCI, this information could ultimately help optimize exercise prescription and provide positive health benefits with exercise as a component of a regular health maintenance routine.

Acknowledgments

This study was funded by a Department of Veterans Affairs Rehabilitation R&D Service Merit Review Award B4027I. The following physical therapists expertly provided our study's intervention component: Naomi Price-Miller, Megan Eyvazzadeh, Jean McQuaid. Gertrude Morrison, RN and Deborah Miller, RN assisted in recruitment of study participants. We acknowledge the help of Richard Macko, MD and Fred Ivey, PhD in the initial design of the study.

All four authors declare no conflict of interest.

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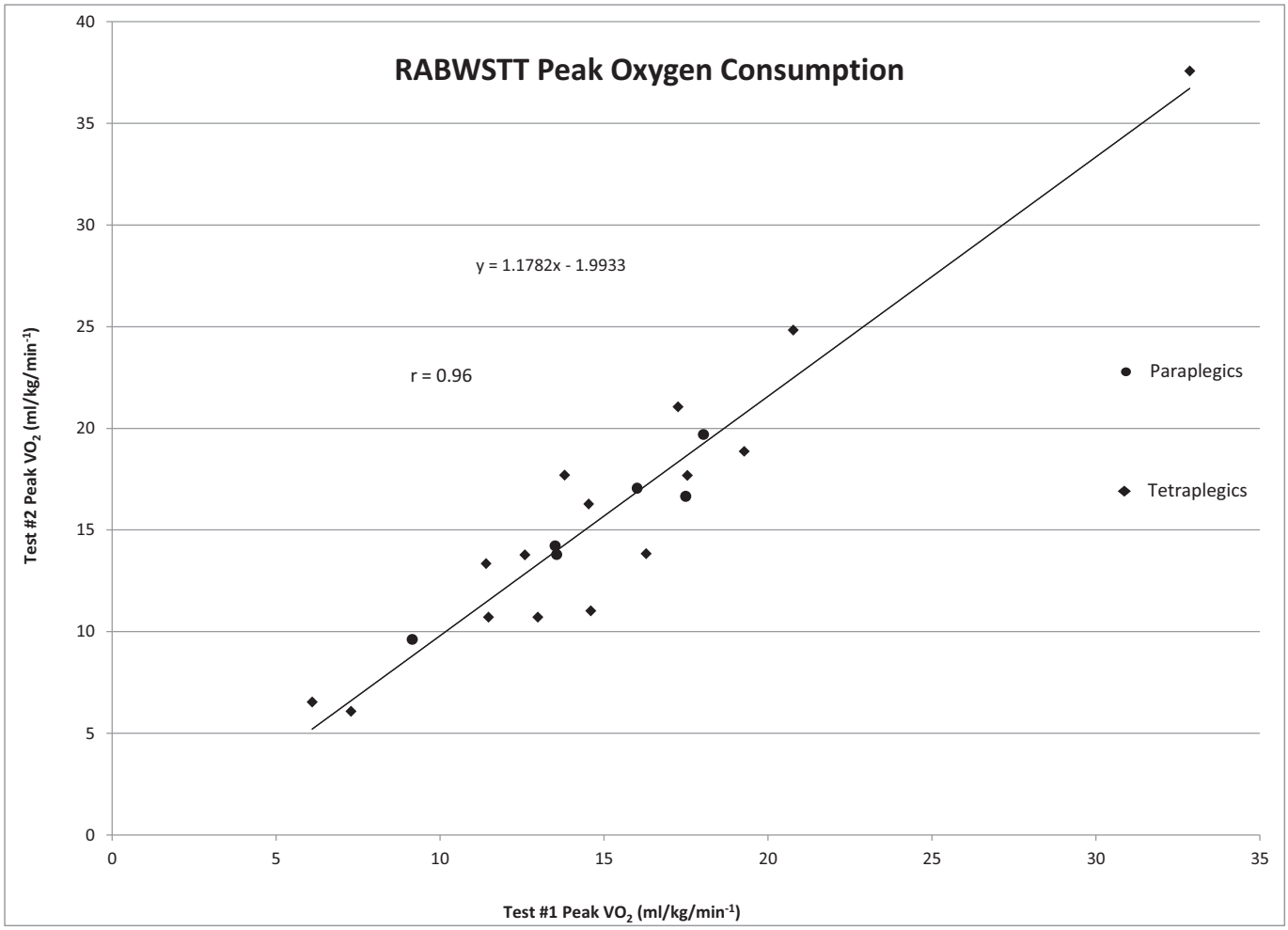
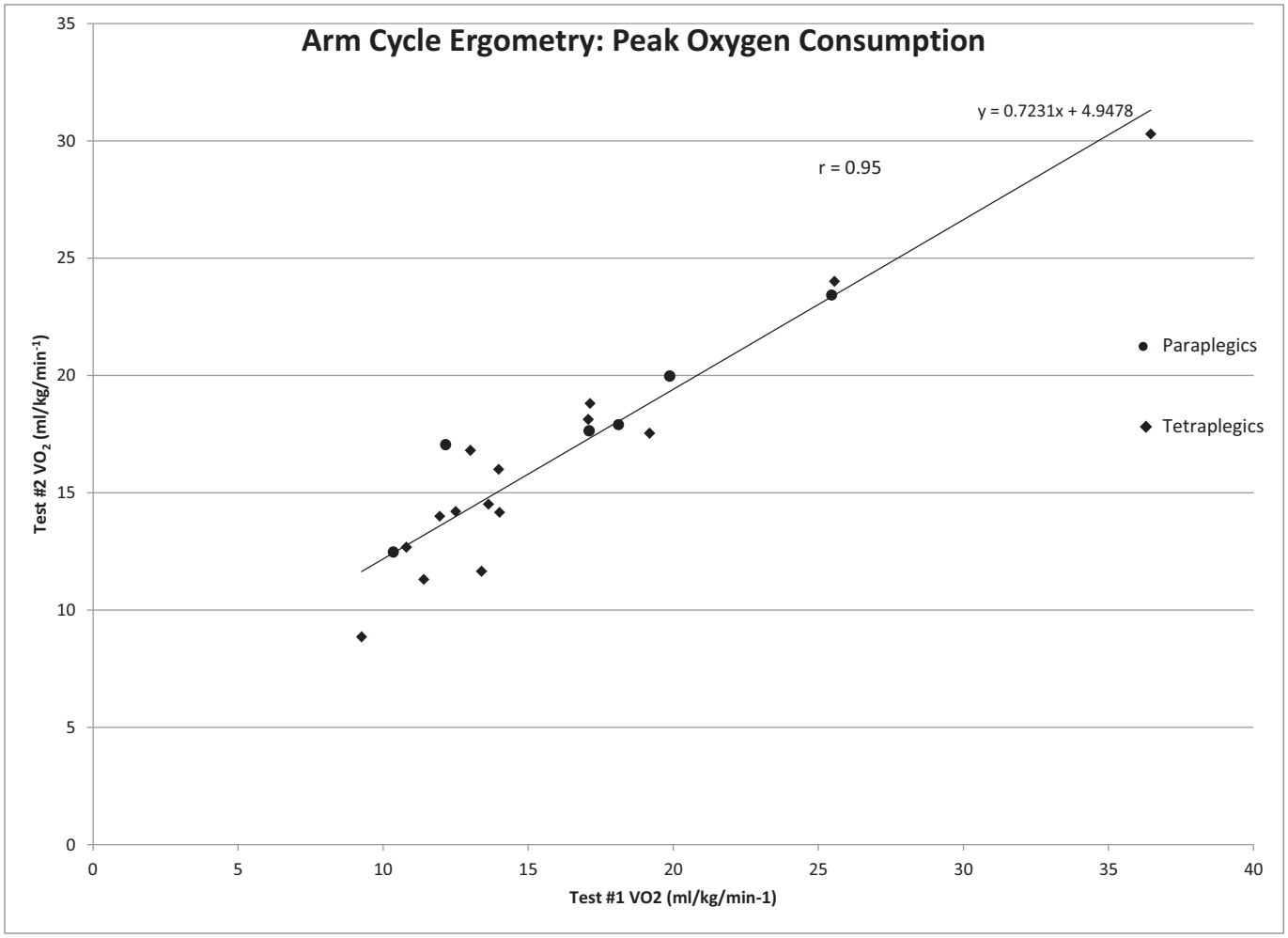
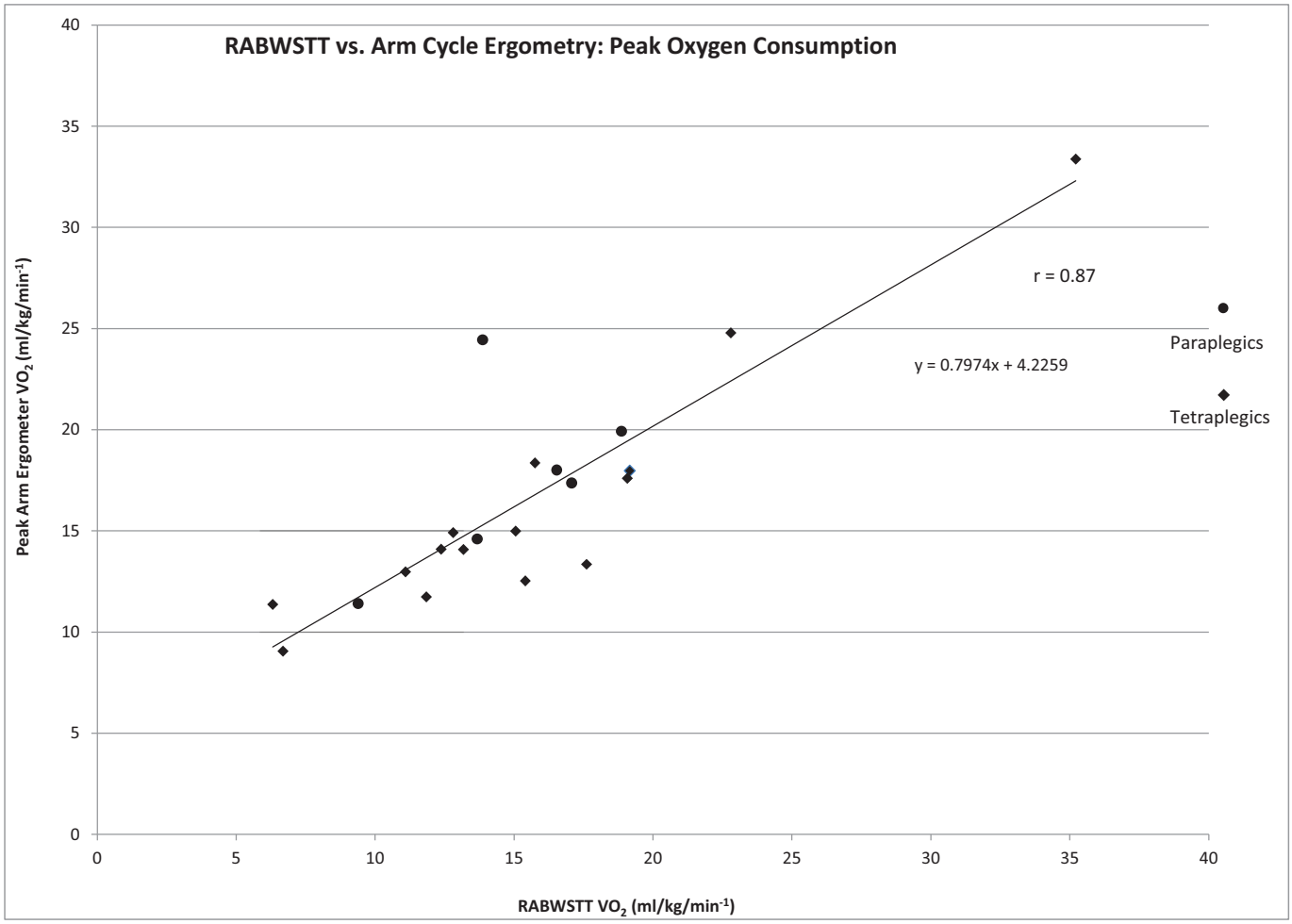
	Mean	Range
Age (years)	51.1 +/-13.7	25-72
Mass (kilograms)	83.3 +/-19.8	45.8-129.8
Body Fat (percent)	33.7 +/-7.6	22.2-44.6
	Injury Level	
Cervical		C1-4=9; C5-8=6
C1-C4	9	
C5-C8	6	
Thoracic		T1-T12
T1-12	5	
Lumbar	1	L2
AIS Classification		
C	2	
D	19	

Table 1. Demographics of 21 participants (19 males, 2 females)


RABWSTT Peak Oxygen Consumption
y = 1.1782x - 1.9933
r = 0.96
Paraplegics
Tetraplegics
Test #2 Peak VO2 (ml/kg/min-1)
Test #1 Peak VO2 (ml/kg/min-1)
0
5
10
15
20
25
30
35
40


Arm Cycle Ergometry: Peak Oxygen Consumption
y = 0.7231x + 4.9478
r = 0.95
Paraplegics
Tetraplegics
Test #2 VO2 (ml/kg/min-1)
Test #1 VO2 (ml/kg/min-1)
0
5
10
15
20
25
30
35
40


RABWSTT vs. Arm Cycle Ergometry: Peak Oxygen Consumption
Peak Arm Ergometer VO2 (ml/kg/min-1)
RABWSTT VO2 (ml/kg/min-1)
r = 0.87
y = 0.7974x + 4.2259
Paraplegics
Tetraplegics
0
5
10
15
20
25
30
35
40

Titles and Legends to Figures

Table 1: Demographic information on the individuals with spinal cord injury in this research protocol.

Figure 1a and 1b: Two pictures illustrating the exercise modalities (Robotic assisted body weight supported treadmill training (RABWSTT) and arm cycle ergometry) and the method implemented in the collection and determination of peak oxygen consumption (VO_2peak).

Figure 2: Test-retest reliability of peak oxygen uptake (VO_2peak) obtained during robotic assisted body weight supported treadmill training (RABWSTT). Each data point represents an individual participant. Diamonds represent individuals with tetraplegia and circles represent individuals with paraplegia.

Figure 3: Test-retest reliability of peak oxygen uptake (VO_2peak) obtained during arm cycle ergometry. Each data point represents an individual participant. Diamonds represent individuals with tetraplegia and circles represent individuals with paraplegia.

Figure 4: Correlation between peak oxygen uptake (VO_2 peak) obtained during RABWSTT and arm cycle ergometry. Values of the x and y coordinates for each participant represent the averages of the two trials for each testing modality.